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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,573	03/25/2004	Arkady Glukhovsky	P-5812-US	5075
49443	7590	06/06/2006	EXAMINER	
PEARL COHEN ZEDEK, LLP 1500 BROADWAY 12TH FLOOR NEW YORK, NY 10036			TOTH, KAREN E	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/808,573

**Applicant(s)**

GLUKHOVSKY, ARKADY

**Examiner**

Karen E. Toth

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/25/04</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear where the device is located

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 4 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 4 discloses that the invention is "immobilized in an esophagus." The human body may not be claimed.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1, 2, 5, 6, 9, 10, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Meron'774 (US Patent Application Publication 2002/0109774).

Regarding Claim 1, Meron'774 discloses a system comprising a device (element 40) with a plurality of sensors (elements 41 and 401) that collect data in the same modality and an element to process the signals (elements 44 and 404) (figure 4; paragraph [0050]; and an external receiving unit (paragraphs [0009] and [0036]).

Regarding Claim 2, Meron'774 further discloses that the plurality of sensors are separated by a distance (Figure 4).

Regarding Claim 5, Meron'774 further discloses that the device comprising the sensors may be swallowed in order to image the GI tract (paragraph [0035]).

Regarding Claim 6, Meron'774 further discloses that the device comprising the sensors may be incorporated a part of an endoscope (paragraph [0033]).

Regarding Claim 9, Meron'774 further discloses that the sensors are image sensors (paragraph [0009] and [0050]).

Regarding Claim 10, Meron'774 further discloses that device comprising the sensors and processing element also comprises a transmitter (element 46) (paragraph [0050]).

Regarding Claim 17, Meron'774 discloses a system comprising means for sampling the output of two sensors (paragraph [0052]), where the sensors are separated by a distance (Figure 4); means for transmitting the output of the sensors (element 46); means for processing the output of the sensors (paragraph [0049]); and means for presenting the output of the sensors (paragraphs [0046] and [0052]).

6. Claims 1-4, 7, 9-13, 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Kilcoyne'138 (US Patent Application Publication 2004/0158138).

Regarding Claim 1, Kilcoyne'138 discloses a system comprising at least two sensors (element 18) collecting the same type of data (paragraphs [0056] and [0132]), a processor (paragraphs [0057] and [0069]) and a receiving unit (element 32).

Regarding Claim 2, Kilcoyne'138 further discloses that the sensors may be separated by a distance (figure 1; paragraph [0056]).

Regarding Claim 3, Kilcoyne'138 further discloses that the sensors may be immobilized in vivo (paragraphs [0075]-[0088]).

Regarding Claim 4, Kilcoyne'138 further discloses that the sensors may be immobilized in an esophagus (paragraphs [0075]-[0088]).

Regarding Claim 7, Kilcoyne'138 further discloses that the sensors may be pH sensors (paragraphs [0063] and [0064]).

Regarding Claim 9, Kilcoyne'138 further discloses that the sensors may be selected from among pressure, temperature, image, blood, and oximetry sensors (paragraph [0128]).

Regarding Claim 10, Kilcoyne'138 further discloses that the system comprises a transmitter (paragraph [0065]).

Regarding Claim 11, Kilcoyne'138 discloses a method comprising inserting two sensors in vivo, where the sensors are separated by a distance and sense the same type of data (paragraphs [0056] and [0132]); and sampling the outputs of the sensors (paragraph [0057]).

Regarding Claim 12, Kilcoyne'138 further discloses processing the output of the sensors (paragraph [0057]).

Regarding Claim 13, Kilcoyne'138 further discloses using pH sensors (paragraphs [0063-0064]).

Regarding Claim 15, Kilcoyne'138 further discloses inserting the sensors into an esophagus (paragraphs [0075]-[0088]).

Regarding Claim 16, Kilcoyne'138 further discloses that performance of the method may be used to diagnose GERD (paragraph [0002]).

Regarding Claim 17, Kilcoyne'138 discloses a system comprising a sampling means for sampling output from two in vivo sensors (paragraphs [0056] and [0057]); the sensors being separated by a distance (paragraphs [0056] and [0132]); means for

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transmitting the output (paragraph [0065]); means for processing the output (paragraphs [0056], [0057], and [0069]); and means for presentation of the output (paragraph [0131]).

7. Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Rich '816 (US Patent Application Publication 2002/0151816).

Regarding Claim 11, Rich '816 discloses a method of measuring an in vivo gradient comprising inserting two sensors that sense the same parameter (element 12) in vivo a distance from each other (Figure 19) (paragraph [0082]); and sampling the output of the sensors (paragraph [0023]).

Regarding Claim 12, Rich '816 further discloses processing the output of the sensors (paragraph [0050]).

Regarding Claim 14, Rich '816 further discloses using the output of the sensors to determine flow (paragraph [0083]).

Regarding Claim 18, Rich '816 discloses a system for determining an in vivo gradient comprising a controller (element 14) that may accept data from a plurality of in vivo sensors, compare the data from each sensor, and determine a fluid flow based on the data (paragraphs [0050] and [0083]).

Regarding Claim 20, Rich '816 further discloses that the data is gathered from two sensors (elements 12) separated by a distance (Figure 19).

Regarding Claim 21, Rich '816 further discloses that the controller determines a cross correlation between the data from the sensors (paragraph [0083]), since the difference between measurements is a form of correlation.

Regarding Claim 22, Rich '816 discloses that the system may be used to calculate a gradient (paragraph [0089]). Direction of fluid flow is determined by the positive or negative results of gradient calculation.

Regarding Claim 23, Rich '816 discloses a method of determining an in vivo gradient comprising accepting data from a plurality of sensors, comparing the data from the sensors, and determining a gradient based on the data (paragraphs [0082-3] and [0089]).

Regarding Claim 25, Rich '816 further discloses that the data is from at least two sensors (element 12) that are separated by a distance (Figure 19).

Regarding Claim 26, Rich '816 further discloses that the comparison determines cross correlation between the data from the sensors (paragraph [0083]), since the difference between measurements is a form of correlation.

Regarding Claim 27, Rich '816 discloses that the system may be used to calculate a gradient (paragraph [0089]). Direction of fluid flow is determined by the positive or negative results of gradient calculation.

Regarding Claim 28, Rich '816 discloses a system comprising an in vivo device (element 136) with a plurality of sensors (element 12) (Figure 19); a controller for determining a gradient based on sampling the sensors (paragraphs [0050], [0083] and

[0089]); and an external device (element 14) to receive data from the sensors (paragraph [0050]).

Regarding Claim 29, Rich '816 further discloses that the in vivo device comprises a transmitter (elements 12 and 16) (paragraph [0049]).

Regarding Claim 31, Rich '816 further discloses that the in vivo device may be immobilized in vivo (paragraphs [0074-8]).

Regarding Claim 33, Rich '816 discloses a in vivo device for measuring an in vivo gradient comprising at least two sensors (element 12) for sensing the same type of data (paragraphs [0082-3] and [0089]); where the device may be immobilized in vivo (paragraphs [0074-8]).

Regarding Claim 36, Rich '816 further discloses that the device comprises a controller (element 14) which is configured to accept and process output from the sensors (paragraph [0050]).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron'774 in view of Kilcoyne'897 (US Patent 6285897).

Regarding Claim 3, Meron'774 discloses all the elements of the current invention, as applied to claims 1, 2, 5, 6, 9, 10, and 17 above, except for the sensors being configured for immobilization in vivo.

Kilcoyne'897 teaches an internal sensing system (element 18) that is configured for in vivo immobilization (Figure 6), in order to enable the user to take measurements from a single location over a period of time.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Meron'774 and configured it for in vivo immobilization, as taught by Kilcoyne'897, in order to enable the user to take measurements from a single location over a period of time.

Regarding Claim 4, Meron'774 discloses all the elements of the current invention, as applied to claims 1, 2, 5, 6, 9, 10, and 17 above, except for the sensors being configured for immobilization in an esophagus.

Kilcoyne'897 teaches an internal sensing system (element 18) that is configured for in vivo immobilization (Figure 6) in a patient's esophagus (element 30), in order to enable the user to take measurements from a single location in the esophagus over a period of time.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Meron'774 and configured it for in vivo immobilization in an esophagus, as taught by Kilcoyne'897, in order to enable the user to take measurements from a single location in the esophagus over a period of time.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne'138 in view of Murata'160 (US Patent 3682160).

Regarding Claim 8, Kilcoyne'138 discloses all the elements of the current invention, as applied to Claims 1-4, 7, 9-13, and 15-17 above, except for the pH sensors being pH sensitive electrodes, pH sensitive color indicators, or ISFET.

Murata'160 further discloses that the pH sensors may be pH sensitive electrodes (column 7, lines 5-7), since the use of these is well known in the art for internally measuring pH.

It would have been obvious to one of ordinary skill in the art to have made the system of Kilcoyne'138 in view of Murata'160, and further used pH sensitive electrodes for sensing pH, as taught by Murata'160, since the use of these is well known in the art for internally measuring pH.

11. Claims 15, 16, 19, 24, 30, 32, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rich '816 in view of Kilcoyne'897.

Regarding Claim 15, Rich'816 discloses all the elements of the current invention, as applied to Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 above, except for the method comprising inserting the sensors into the esophagus of a patient.

Kilcoyne'897 teaches a method of internal sensing comprising inserting sensors (element 18) into the esophagus of a patient (element 30) (Figure 6), in order to measure the patient's gastroesophageal reflux.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Rich'816 and included insertion of the sensors in the esophagus of a patient, as taught by Kilcoyne'897, in order to measure the patient's gastroesophageal reflux.

Regarding Claim 16, Rich'816 discloses all the elements of the current invention, as applied to Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 above, except for the method comprising using the sensor output to diagnose the presence or absence of gastroesophageal reflux disease.

Kilcoyne'897 teaches a method of internal sensing comprising measurement of a patient's gastroesophageal reflux (column 1, lines 6-10), in order to properly diagnose and treat a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Rich'816 and included diagnosis of gastroesophageal reflux disease, as taught by Kilcoyne'897, in order to properly diagnose and treat a patient.

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Regarding Claim 19, Rich'816 discloses all the elements of the current invention, as applied to Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 above, except for the data being pH data.

Kilcoyne'897 teaches an internal sensing system (element 18) that may be used to sense the pH of a patient (column 3, lines 24-26), in order to detect gastroesophageal reflux disease.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Rich'816 and collected pH data, as taught by Kilcoyne'897, in order to detect gastroesophageal reflux disease.

Regarding Claim 24, Rich'816 discloses all the elements of the current invention, as applied to Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 above, except for the data being pH data.

Kilcoyne'897 teaches an internal sensing system (element 18) that may be used to sense the pH of a patient (column 3, lines 24-26), in order to detect gastroesophageal reflux disease.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Rich'816 and collected pH data, as taught by Kilcoyne'897, in order to detect gastroesophageal reflux disease.

Regarding Claim 30, Rich'816 discloses all the elements of the current invention, as applied to Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 above, except for the sensors being pH sensors.

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Kilcoyne'897 teaches an internal sensing system (element 18) that may be used to sense the pH of a patient (column 3, lines 24-26), in order to detect gastroesophageal reflux disease.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Rich'816 with pH sensors, as taught by Kilcoyne'897, in order to detect gastroesophageal reflux disease.

Regarding Claim 32, Rich'816 discloses all the elements of the current invention, as applied to Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 above, except for the in vivo device comprising the controller.

Kilcoyne'897 teaches an in vivo sensing device (element 18) that may contain a microprocessor (column 3, lines 17-19) for processing the measured data, so that less external processing of results is required.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Rich'816 and included the controller in the in vivo element, as taught by Kilcoyne'897, so that less external processing of results is required.

Regarding Claim 34, Rich'816 discloses all the elements of the current invention, as applied to Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 above, except for the sensors being pH sensors.

Kilcoyne'897 teaches an internal sensing system (element 18) that may be used to sense the pH of a patient (column 3, lines 24-26), in order to detect gastroesophageal reflux disease.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Rich'816 with pH sensors, as taught by Kilcoyne'897, in order to detect gastroesophageal reflux disease.

Regarding Claim 35, Rich'816 discloses all the elements of the current invention, as applied to Claims 11, 12, 14, 18, 20-23, 25-29, 31, 33, and 36 above, except for the device being configured for immobilization within an esophagus.

Kilcoyne'897 teaches an internal sensing system (element 18) that is configured for in vivo immobilization (Figure 6) in a patient's esophagus (element 30), in order to enable the user to take measurements from a single location in the esophagus over a period of time.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Rich'816 and configured it for in vivo immobilization in an esophagus, as taught by Kilcoyne'897, in order to enable the user to take measurements from a single location in the esophagus over a period of time.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

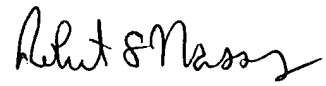
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ROBERT L. NASSER  
PATENT EXAMINER